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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,164	09/09/2003	Randal Lee Schapaugh	00373.US1	5673
25533	7590	09/05/2007		
PHARMACIA & UPJOHN 7000 Portage Road KZO-300-104 KALAMAZOO, MI 49001			EXAMINER WALLENHORST, MAUREEN	
			ART UNIT 1743	PAPER NUMBER
			MAIL DATE 09/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/658,164

Applicant(s)

SCHAPAUGH ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-11,13-17,19-24,27,29-32,35 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 and 36 is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-11, 13-17, 19, 21-24, 27, 29-32, 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite since it recites the same exact limitations as claim 22, and therefore, it does not further limit claim 22.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-2, 5-11, 13-17, 19, 21-24, 27, 29-30 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-26, 28 and 33-36 of copending Application No. 10/658,165 in view of Andonaegui et al (article submitted in the Information Disclosure Statement filed on March 3, 2004). Claims 1-3, 5-26, 28 and 33-36 of U.S. Application serial no. 10/658,165 recite a method of characterizing the transfer of an analyte from a non-aqueous liquid composition to an aqueous dissolution medium comprising the steps of providing a non-aqueous liquid composition comprising an analyte and a non-aqueous base, combining the non-aqueous liquid composition with an aqueous dissolution medium, agitating and mixing the non-aqueous liquid composition and the aqueous dissolution medium and determining the amount of analyte in the aqueous dissolution medium at multiple time points after the combining and agitating steps. The claims of U.S. application serial no. 10/658,165 fail to recite that a non-aqueous diluent is added to the non-aqueous liquid composition prior to being mixed with the aqueous dissolution medium.

Andonaegui et al teach of an in vitro test for studying the in vivo performance of sustained release tablets containing theophylline therein as administered under a fasting condition and with a high fat diet. Andonaegui et al teach that tablets having a non-aqueous lipid matrix and theophylline therein are combined with an aqueous dissolution medium such as water, simulated gastric fluid, and aqueous mediums with gradual pH changes in a dissolution apparatus such as a paddle assembly. Theophylline dissolved into the aqueous dissolution medium after a predetermined time is analyzed by UV spectrophotometry. Andonaegui et al teach that in order to simulate the in vivo action of the theophylline drug under the condition of a high fat diet, the tablet is pretreated or diluted with peanut oil before being combined with the

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aqueous dissolution medium. Changes produced in the in vivo absorption profile of the drug by a high fat diet are correlated better with a pretreatment of the tablets with peanut oil followed by a dissolution test using an aqueous medium. See pages 1199-1200 and 1203 of Andonaegui et al.

Based upon the combination of claims 1-3, 5-26, 28 and 33-36 in U.S. application serial no. 10/658,165 and Andonaegui et al., it would have been obvious to one of ordinary skill in the art at the time of the instant invention to dilute the non-aqueous liquid composition recited in the claims of U.S. application serial no. 10/658,165 with a non-aqueous diluent before combining the non-aqueous liquid composition with an aqueous dissolution medium for dissolution testing in order to simulate an in vivo condition of the analyte in the non-aqueous liquid composition under a high fat diet, as taught by Andonaegui et al.

This is a provisional obviousness-type double patenting rejection.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-2, 5-11, 13-17, 19, 21-24, 27, 29-31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schapaugh et al (US 2004/0115822) in view of Andonaegui et al (article submitted in the Information Disclosure Statement filed on March 3, 2004). For a teaching of Andonaegui et al, see previous paragraphs in this Office action.

Schapaugh et al teach of a method for measuring the dissolution rate of an analyte in a non-aqueous liquid composition. The method comprises the steps of providing a non-aqueous liquid composition comprising an analyte and a non-aqueous base, combining the non-aqueous liquid composition with an aqueous dissolution medium, agitating the non-aqueous liquid composition and the aqueous dissolution medium, and determining the amount of analyte in the aqueous dissolution medium at different points in time. Schapaugh et al also teach that the aqueous dissolution medium can be filtered through a filter before determining the amount of analyte therein. Preferably, the non-aqueous liquid composition is a sustained release pharmaceutical composition having ceftiofur as the analyte therein and oil such as cottonseed oil as the aqueous base. The non-aqueous liquid composition is a suspension, solution or emulsion, and the agitation is conducted until from about 10%-100% of the total amount of analyte has been dissolved in the aqueous dissolution medium. The aqueous dissolution medium can contain a buffer such as a phosphate buffer having a molarity from 0.001 molar (1mM) to 0.1 molar (100 mM) and a pH of 6 to 8. The ratio of the non-aqueous liquid composition to the aqueous dissolution medium varies from about 1:100 to about 1:2000 by volume. See paragraph nos. 0037-0038 and 0046, and the claims in Schapaugh et al. The reference to Schapaugh et al qualifies as prior art against the instant claims under 35 USC 102(e) since the effective filing date of this reference (September 12, 2002) is prior to the effective filing date of the instant

application (November 27, 2002), and the reference to Schapaugh et al has a different inventive entity than the instant application. Schapaugh et al fail to teach that a non-aqueous diluent is added to the non-aqueous liquid composition prior to being mixed with the aqueous dissolution medium.

Based upon the combination of Schapaugh et al and Andonaegui et al., it would have been obvious to one of ordinary skill in the art at the time of the instant invention to dilute the non-aqueous liquid composition taught by Schapaugh et al with a non-aqueous diluent before combining the non-aqueous liquid composition with an aqueous dissolution medium for dissolution testing in order to simulate an in vivo condition of the analyte in the non-aqueous liquid composition under a high fat diet, as taught by Andonaegui et al.

8. Claims 1-2, 5-11, 13-17, 19, 21-24, 27, 29-32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al (US Patent no. 5,721,359, submitted in the IDS filed on March 3, 2004) in view of both Andonaegui et al (article submitted in the IDS filed on March 3, 2004) and Conti et al (article submitted in the IDS filed on March 3, 2004). For a teaching of Andonaegui et al, see previous paragraphs in this Office action.

Dunn et al teach of a non-aqueous liquid composition containing a non-aqueous base and an analyte. The non-aqueous base is oil such as corn oil, peanut oil, sesame oil, olive oil, safflower oil, soybean oil, cottonseed oil, rapeseed oil and mixtures thereof. Preferably, the non-aqueous base is cottonseed oil. The analyte is a cephalosporin antibiotic material known as ceftiofur. The non-aqueous liquid composition is used as a pharmaceutical composition in a sustained release dosage form. The pharmaceutical composition can also contain excipients such as dispersing agents, emulsifying agents, buffers, sweeteners, flavoring agents, colorants and

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preservative agents. See lines 10-39 in column 3 and lines 21-31 in column 9 of Dunn et al. In example 4 of Dunn et al, a sustained release oil formulation containing ceftiofur free acid and cottonseed oil is taught. In example 7 of Dunn et al, an in vitro dissolution test of the ceftiofur oil suspension formulation is disclosed in order to characterize the in vivo performance of this pharmaceutical composition for public use. In the dissolution test, samples of the non-aqueous liquid oil composition containing ceftiofur antibiotic are loaded into a dissolution apparatus containing an aqueous dissolution medium at an optimal pH of 7. The non-aqueous liquid composition and the aqueous dissolution medium are agitated with a rotating paddle, and at different time points after being combined together, samples of the aqueous dissolution medium are taken and tested for the amount of ceftiofur analyte therein. See Figure 6 in Dunn et al that plots the amount of ceftiofur analyte released into the aqueous dissolution medium as a function of time. Dunn et al fail to teach that a non-aqueous diluent is added to the non-aqueous liquid composition prior to being mixed with the aqueous dissolution medium, and fail to teach that the aqueous dissolution medium contains a buffer of a certain molarity.

Conti et al teach of in vitro dissolution tests for different drug delivery systems. Four different types of dissolution methods and apparatuses are evaluated including a paddle stirring apparatus, a rotating bottle apparatus, a shaker incubator and a recycling flow through cell. In each of these devices, the aqueous dissolution medium used is an aqueous phosphate buffered solution at an optimal pH of 7.4. In some of the tests performed, the surfactant Polysorbate 20 is added to the aqueous dissolution medium. In each of the dissolution tests, samples of the aqueous dissolution medium are taken at different time points after being admixed with a drug formulation, then are filtered through a Millipore membrane having 0.22 micron pores, and

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analyzed by UV spectrophotometry. See pages 1224-1226 in Conti et al. Conti et al teach that the presence of a surfactant in the aqueous dissolution medium doubles the amount of drug released into the dissolution medium for all of the methods tested. Faster drug release is also found for the aqueous dissolution medium containing a phosphate buffer at pH 7.4 and at a high ionic strength.

Based upon the combination of Dunn et al and Andonaegui et al., it would have been obvious to one of ordinary skill in the art at the time of the instant invention to dilute the non-aqueous liquid composition taught by Dunn et al with a non-aqueous diluent before combining the non-aqueous liquid composition with an aqueous dissolution medium for dissolution testing in order to simulate an in vivo condition of the analyte in the non-aqueous liquid composition under a high fat diet, as taught by Andonaegui et al.

Based upon the combination of Dunn et al and Conti et al, it would have been obvious to one of ordinary skill in the art to use a phosphate buffered aqueous solution as the aqueous dissolution medium in the dissolution method taught by Dunn et al since Conti et al disclose that such a phosphate buffered dissolution medium serves to produce faster drug release from a drug formulation into the aqueous medium, and that a phosphate buffer at a high ionic strength, which is determined by the molarity of the phosphate buffer, produces an even faster drug release into an aqueous dissolution medium. Since concentration is a result effective variable, one of ordinary skill in the art at the time of the instant invention would have found it obvious to vary the molarity of the phosphate buffer used as an aqueous dissolution medium in a dissolution test to the values recited in instant claim 1 in order to optimize the action of the aqueous dissolution medium for dissolving a drug for analysis. With regards to instant claims 30-31, it would have

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been obvious to one of ordinary skill in the art to vary the ratio of the non-aqueous liquid composition to the aqueous dissolution medium taught by Dunn et al to the levels recited since the amount of materials used in a method is a result effective variable that can be experimentally varied in order to optimize a particular procedure being performed with the materials.

9. Claim 20 and 36 are allowable over the prior art of record since none of the prior art of record teaches or fairly suggests diluting a non-aqueous liquid composition comprising an analyte/drug with a hydrogenated coconut oil or a modified cottonseed oil prior to testing the non-aqueous liquid composition in a dissolution testing apparatus containing an aqueous dissolution medium.

10. Applicant's arguments filed June 6, 2007 have been fully considered but they are not persuasive.

The previous rejections of the claims under 35 USC 112, second paragraph made in the last Office action mailed on March 6, 2007 have been withdrawn in view of Applicants' amendments to the claims. Amended claim 23, however, is rejected under 35 USC 112, second paragraph, for the reasons set forth above, as necessitated by Applicants' amendment to the claim.

Applicants argue the rejection of the claims under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims in application serial no. 10/658,165 in view of Andonaegui et al by stating that application no. 10/658,165 is fundamentally different from the present application in that in application no. 10/658,165, an emulsion is produced while in the instant invention, an emulsion does not form. Applicants argue that in application no. 10/658,165, a shaker apparatus is used to prepare the emulsion, while in

the instant invention, a paddle assembly is used to spread the non-aqueous medium on the surface of the aqueous dissolution medium to form two distinct, continuous liquid phases in contact with each other. Applicants also argue that in the reference to Andonaegui et al, the rate of dissolution from a solid phase to a liquid phase is measured, and thus, neither Andonaegui et al nor application serial no. 10/658,165 teach of two distinct continuous liquid phases in contact with each other. In response to these arguments, it is noted that a rejection made under the doctrine of obviousness-type double patenting is based upon what the claims in an application recite, not what the specification or figures disclose. Independent claims 1 and 35 in the instant application only recite a broad "dissolution testing apparatus" for contacting the non-aqueous liquid composition with the aqueous dissolution medium, and this "dissolution testing apparatus" could be a shaker apparatus that forms an emulsion, as recited in the claims of application no. 10/658,165. The independent claims in the instant application do not specifically recite that a paddle assembly is used to combine the non-aqueous liquid composition with the aqueous dissolution medium. In addition, the instant claims do not positively recite that two continuous liquid phases are formed between the non-aqueous liquid composition and the aqueous dissolution medium since the "dissolution testing apparatus" is not defined as a paddle assembly where the non-aqueous composition forms an even layer on the surface of the dissolution medium. Additionally, the secondary reference to Andonaegui et al is not relied upon for a teaching of a dissolution test between a non-aqueous liquid composition and an aqueous dissolution medium since the claims in application no. 10/658,165 primarily teach this. Rather, the reference to Andonaegui et al is relied upon for its teaching of diluting an analyte whose

dissolution rate is being measured in order to simulate an in vivo condition of the analyte under a high fat diet.

Applicants argue the rejection of the claims under 35 USC 103 as being obvious over Schapaugh et al (US 2004/0115822, corresponding to application serial no. 10/658,165) in view of Andonaegui et al using the same arguments as presented above for the obviousness-type double patenting rejection. See the Examiner's response to these arguments in the preceding paragraph. Applicants also argue that the publication to Schapaugh et al is not prior art against the instant claims under any section of 35 USC 102, particularly 35 USC 102(e)(1) since the present invention was constructively reduced to practice on the exact day when US 2004/0115822 was filed, and therefore, both the instant application and US 2004/0115822 were filed on the same day. In response to this argument, it is noted that the effective US filing date of Schapaugh et al (US 2004/0115822) is September 12, 2002 when provisional application serial no. 60/410,147 was filed. This is considered the day that the invention described in Schapaugh et al was constructively reduced to practice. Similarly, the effective US filing date of the instant application is November 27, 2002 when provisional application serial no. 60/429,260 was filed. This is considered the day that the invention described in the instant application was constructively reduced to practice. 35 USC 102(e)(1) states that publications of patent applications are considered to be prior art as of their earliest effective US filing date, and since the earliest effective US filing date of Schapaugh et al (i.e. September 12, 2002) is earlier than the earliest effective US filing date of the instant application (i.e. November 27, 2002), Schapaugh et al qualifies as prior art under 35 USC 102(e)(1) against the instant claims.

Applicants argue the rejection of the claims under 35 USC 103 as being obvious over Dunn et al in view of Conti et al and Andonaegui et al by stating that in the instant invention, the non-aqueous liquid medium spreads as an even layer on the surface of the aqueous dissolution medium, whereas in Dunn et al, the non-aqueous composition is separated from the aqueous dissolution medium by a dialysis membrane, and therefore, Dunn et al do not teach of two distinct continuous liquid phases in contact with each other. Applicants also argue that both Conti et al and Andonaegui et al measure the rate of dissolution from a solid phase to a liquid phase, and therefore, also do not teach of the forming two distinct continuous liquid phases in contact with each other. In response to these arguments, it is noted that Applicants are arguing limitations that are not present in the claims as presently written. Nowhere in the claims is the presence of two distinct continuous liquid phases in contact with each other recited. Rather, a broad dissolution testing apparatus is recited in the claims, which could include the dissolution cell sealed with a dialysis membrane taught by Dunn et al. Nothing in the instant claims distinguishes the "dissolution testing apparatus" from the dissolution apparatus taught by Dunn et al. In addition, the secondary references to Conti et al and Andonaegui et al are not required to disclose two distinct continuous liquid phases in contact with each other since this limitation is not positively recited in the instant claims, and the primary reference to Dunn et al teaches of a dissolution test between a non-aqueous liquid composition and an aqueous dissolution medium.

For all of the above reasons, Applicants' arguments are not found persuasive.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

August 22, 2007

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP 1700